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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/620,392	07/19/00	BOUKHAROV	A 04983.0130.N

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EXAMINER	
ZHOU, S	
ART UNIT	PAPER NUMBER
1631	12

DATE MAILED: 09/25/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/620,392	Applicant(s) BOUKHAROV ET AL.	
	Examiner Shubo "Joe" Zhou	Art Unit 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 July 2001, and 9/12/2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4, and 6-20* is/are pending in the application.

4a) Of the above claim(s) *10-15* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,6-9 and 16-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-4, and 6-20* are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *11* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Applicants' election, with traverse, of Group I (original claims 1-9), drawn to nucleic acids, and SEQ ID NO:1, in Paper No. 8, filed 7/17/01, and Paper No. 10, filed 9/12/01, is acknowledged. Applicants' amendments of adding claims 16-20, etc. in the same Papers are acknowledged and entered.

Applicants traverse that the Office has not proven that it would impose undue search burden to the Office if all the Groups are co-examined. This is not found persuasive because the traverse is not directed to the reasons for distinctness of the Groups of inventions as set forth in the Office action mailed 6/8/01. Reasons for distinctness of Group I and Group II were set forth in the fourth paragraph, page 3 of the Office action. Further, the traverse is not directed to the reasons of would-be undue search burden for co-examination of all the groups as set forth in the fifth paragraph at page 3 of the Office action. In summary, the traverse is not persuasive due to not being directed to the reasoning for the Group election requirement. The restriction requirement is still deemed proper and is, therefore, made FINAL.

Accordingly, claims 1-4, and 6-20 are currently pending, but only claims 1-4, 6-9, and 16-20 are under examination by the Office in the currently action, and claims 10-15 are withdrawn from further consideration as being drawn to non-elected inventions.

Specification

The specification is objected to because of the following:

The disclosure is objected to because it contains an embedded hyperlink and/or other form or browser-executable code. Such code is present in the specification at page 9, and/or elsewhere. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP ' 608.01.

Appropriate correction is required.

Claim Rejections-35 USC § 101 and § 112

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The pending claims have been reviewed in light of the Utility Examination Guidelines and Guidelines for Examination of Patent Applications under 35 U.S.C. 112, first paragraph, Written Description Requirement, Federal Register, Vol. 66, No. 4, pages 1092-1111, Friday, January 5, 2001.

The examiner is using the following definitions in evaluating the claims for utility.

"Specific" - A utility that is *specific* to the subject matter claimed. This contrasts with a *general* utility that would be applicable to the broad class of the invention.

"Substantial" - A utility that defines a "real world" use. Utilities that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use are not substantial utilities.

"Credible" - Credibility is assessed from the perspective of one of ordinary skill in the art in view of the disclosure and any other evidence of record that is probative of the

applicant's assertions. That is, the assertion is an inherently unbelievable undertaking or involves implausible scientific principles.

"Well-established" - a specific, substantial, and credible utility which is well known, immediately apparent, or implied by the specification's disclosure of the properties of a material, alone or taken with the knowledge of one skilled in the art.

See also the MPEP at §§ 2107 - 2107.02.

Claims 1-4, 6-9, and 16-20 are rejected under 35 U.S.C. 101 because the claimed invention lacks patentable utility due to its not being supported by a specific, substantial, and credible utility or, in the alternative, a well-established utility.

The claimed nucleic acids are not supported by a specific asserted utility because the disclosed uses of these nucleic acids are generally applicable to rice genomic nucleic acid. The specification states that the nucleic acid compounds are useful for gene mapping, marker assisted introgresson of traits, physical mapping, etc. (pages 9 and 49). All these possible uses are generic to any rice nucleic acid sequences.

Further, the claimed nucleic acids are not supported by a substantial utility because no substantial utility has been established for the claimed subject matter. For example, a nucleic acid may be utilized to obtain a protein. The protein could then be used in conducting research to functionally characterize the protein to elucidate biochemical pathways and to screen for biologically active agents. Also, it need further research to discover the markers, such as SNPs. The apparent need for such research clearly indicates that the protein and/or its function is not disclosed as to a currently

available or substantial utility. A starting material that can only be used to produce a final product does not have substantial asserted utility in those instances where the final product is not supported by a specific and substantial utility. In this case none of the proteins that are to be produced as final products resulting from processes involving claimed nucleic acid have asserted or identified specific and substantial utilities. The research contemplated by applicant(s) to characterize the markers, etc., does not constitute a specific and substantial utility. Identifying and studying the properties of a protein itself or the mechanisms in which the protein is involved does not define a "real world" context for use. Similarly, the other listed and asserted utilities as summarized above or in the instant specification are neither substantial nor specific due to being generic in nature and applicable to a myriad of such compounds.

Please note, because the claimed invention is not supported by a specific and substantial asserted utility for the reasons set forth above, credibility has not been assessed.

Neither the specification as filed nor any art of record discloses or suggests any property or activity for the nucleic acid and/or protein compound(s) such that another non-asserted utility would be well established for the nucleic acid compounds.

The following is a quotation of the **first** paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-4, 6-9, and 16-20 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention lacks patentable utility due to its not being supported by a specific, substantial, and credible utility or, in the alternative, a well-established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Claims 1-4, 6-9, and 16-20 are rejected, as discussed below, also under 35 U.S.C. 112, first paragraph, as containing subject matter which lacks written description in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 1-4, 6-9, and 16-20 are drawn to nucleic acids comprising the sequence of the claimed SEQ ID NO:1. The instant specification only discloses species, i.e. the DNA sequence of the SEQ ID NO. However, given the broad scope of the claims, they are drawn to a genus: any nucleic acid that minimally contains the sequences of the claimed SEQ ID NO, including any full length gene which contain the sequence, any fusion constructs, any RNAs or cDNAs, etc. There is substantial variability among the species of polynucleotides or nucleic acids encompassed within the scope of the claims because the claimed SEQ ID NO is only fragment of any full-length gene or cDNA species, or any vector due to the use of the open language "comprising". Since the claimed genus encompasses species yet to be discovered, DNA constructs that encode fusion proteins, etc., the mere disclosure of a species: sequence of the claimed SEQ ID NO, does not provide an adequate description of the claimed genus. In view of the level of knowledge and skill in the art, one skilled in the art would not recognize from the

disclosure that the applicant was in possession of the genus of DNAs or RNAs encompassed in claims 1-4, 6-9, and 16-20, which comprises the sequence of the claimed SEQ ID NO.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention.* The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.)

With the exception of SEQ ID NO:1 , the skilled artisan cannot envision the detailed chemical structure of the encompassed polynucleotides/nucleic acids, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. The nucleic acid itself is required. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) and Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016. In Fiddes v. Baird, 30 USPQ2d 1481, 1483, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence.

Finally, University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404, 1405 held that:

> ...To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." *Lockwood v. American Airlines, Inc.* , 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); *In re Gosteli* , 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc.,

that set forth the claimed invention." *Lockwood* , 107 F.3d at 1572, 41 USPQ2d at 1966.

An adequate written description of a DNA, such as the cDNA of the recombinant plasmids and microorganisms of the '525 patent, "requires a precise definition, such as by structure, formula, chemical name, or physical properties," not a mere wish or plan for obtaining the claimed chemical invention. *Fiers v. Revel* , 984 F.2d 1164, 1171, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993). Accordingly, "an adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself." Id. at 1170, 25 USPQ2d at 1606.

The name cDNA is not itself a written description of that DNA; it conveys no distinguishing information concerning its identity. While the example provides a process for obtaining human insulin-encoding cDNA, there is no further information in the patent pertaining to that cDNA's relevant structural or physical characteristics; in other words, it thus does not describe human insulin cDNA. Describing a method of preparing a cDNA or even describing the protein that the cDNA encodes, as the example does, does not necessarily describe the cDNA itself. No sequence information indicating which nucleotides constitute human cDNA appears in the patent, as appears for rat cDNA in Example 5 of the patent. Accordingly, the specification does not provide a written description of the invention of claim 5.

Therefore, only SEQ ID NO:1, but not the full breadth of the claim meet the written description provision of 35 USC 112, first paragraph. The species specifically disclosed is not representative of the genus because the genus is highly variant.

Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 USC 112 is severable from its enablement provision (See page 1115).

In summary, claims 1-4, 6-9, and 16-20 contain subject matter which lacks written description in the specification in such a way as to enable one skilled in the art to make and/or use the invention.

For reasons stated above, claims 1-4, 6-9, and 16-20 are rejected under 35 U.S.C. 112, first paragraph, also because the specification, while being enabling for

polynucleotides/nucleic acids of the elected SEQ ID NO:1, in claims 1-4, 6-9, and 16-20, does not reasonably provide enablement for the full breadth of the claim. Thus, the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Claim Rejections-35 USC § 112

The following is a quotation of the **second** paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-4, 6-9, and 16-20 are rejected under 35 U.S.C. 112 , second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The phrase "complements" in claim 1, 2, 17 and all their dependent claims is vague and confusing, and makes the claims indefinite. The metes and bounds of the claims are unclear because it is not known what is meant by "complements". One explanation is the full complement of the entire sequence in a particular SEQ ID NO, or it can be interpreted as any percentage of complement, e.g. 10%, or 80%, of a sequence in the SEQ ID NO.

The recitation of Table 1 in claim 16 is vague and makes the claim indefinite. There is no guarantee that the information contained in Table will not change and therefore the metes and bounds of the claim is unclear.

Claims 6-9 are indefinite because they are dependent from a canceled claim 5.

Claim Rejections-35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> **A person shall be entitled to a patent unless –**
>
> **(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.**
>
> **(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.**

Claims 1-2, and 17-18 are rejected under 35 U.S.C. § 102 (b) as being anticipated by Birren et al. (Genbank accession No. AC005922, 11/14/1998).

Birren et al. disclose a sequence comprising a stretch of 22 bp that is completely complementary to SEQ ID NO:1. See alignment. The 22 bp sequence is 100% identical to the complement of SEQ ID NO:1, as required in the instant claims. The sequence disclosed by Birren et al. also comprises a fragment of about 100 bp that is complementary to the complement of SEQ ID NO:1, as required in the instant claim. Note that the complete sequence disclosed by Birren et al. is not provided but is available to the public in the GenBank database. Applicants are informed that any percentage of complementarity is interpreted as a complement, and that any length of a fragment including two or more amino acid residues is interpreted as a fragment of the protein, absent a clear definition for the terms in the instant specification.

Claim 3 is rejected under 35 U.S.C. § 102 (b) as being anticipated by Su et al. (Genbank accession No. AF015462, 7/16/1998).

Su at al. disclose a sequence that is complementary to SEQ ID NO:1, and it contains a microsatellite sequence, as required in the instant claim.

Claims 4 and 9 are rejected under 35 U.S.C. § 102 (b) as being anticipated by Alonso et al. (Genbank accession No. X74737, 1/21/1999).

Alonso et al. disclose a bacterial sequence that is complementary to the sequence of SEQ ID NO:1, that comprises many single nucleotide polymorphisms and that encode a protein that is a homologue of a fragment of the rice protein encoded by SEQ ID NO:1, as required in the claims. Note that any single nucleotide difference between two sequences is interpreted as single nucleotide polymorphism absent evidence to the contrary.

Claim 6 is rejected under 35 U.S.C. § 102 (a) as being anticipated by Wright et al. (Geneseq accession No. AAZ35275, 3/27/2000).

Wright et al. disclose a sequence from soybean, a dicot plant, comprising 19 bp that is identical to a fragment of SEQ ID NO:1 and therefore encoding a fragment of the protein encoded by SEQ ID NO:1 (see alignment). Note that any length of a fragment including two or more amino acid residues are interpreted as a fragment of the protein absent a clear definition of the term fragment.

Claims 7-8 are rejected under 35 U.S.C. § 102 (b) as being anticipated by Baba et al. (GenBank accession No. E03435, 9/29/1997).

Baba et al. disclose a sequence from Zea mays, a non-rice monocot, encoding a fragment of the protein encoded by SEQ ID NO:1, and the protein is a non-rice monocot, as required in the instant claims. The Zea mays fragment is interpreted being the non-rice cereal homologue of a fragment of the rice protein encoded by SEQ ID NO:1, as required in the instant claim. Note that any length of a fragment including two or more amino acid residues are interpreted as a fragment of the protein absent a clear definition of the term fragment.

It should be pointed out that most of the 102 rejections set forth above is due to a lack of clear definitions for the terms "complement" and "fragment" in the instant specification.

Conclusion

No claim is allowed.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703) 308-4242 or (703)305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to:
Shubo "Joe" Zhou, Ph.D., whose telephone number is (703) 605-1158. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (703) 308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to Patent Analyst Tina Plunkett whose telephone number is 703)-305-3524, or to the Technical Center receptionist whose telephone number is (703) 308-0196.

S. "Joe" Zhou, Ph.D.

Patent Examiner

ARDIN H. MARSCHEL
PRIMARY EXAMINER